REMARKS

With this response, claims 1-2 and 7-17 are pending. Claims 3-6 have been cancelled without prejudice or disclaimer to the underlying subject matter. Claims 1-2 have been amended, and new claims 7-17 have been added. Applicants do not believe that any fees are due at this time. However, should any fees be required for any reason relating to this document, the Commissioner is authorized to deduct the fees from Arnold & Porter Deposit Account No. 50-1824.

I. Restriction Requirement

Applicants maintain that the restriction of Claims 1-6 is improper. Applicants assert that the complete examination of the application would be handled most expeditiously by treating all of the pending claims as a single entity. More particularly, the search of nucleic acid molecules, the enzymes they encode, and transformed plants including said nucleic acid molecules would clearly be most efficiently searched together. As Section 803 of the MPEP directs, "[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions." Moreover, a serious burden would arise if the application remains restricted. For the foregoing reasons, Applicants maintain their traversal of the restriction requirement.

II. Rejection under 35 USC § 101, Utility

Claims 1-2 stand rejected under 35 USC § 101 for allegedly not being supported by either specific and/or substantial utility, or a well-established utility. This rejection is respectfully traversed for the reasons which follow.

In support of this rejection, the Office Action asserts:

> [t]he claimed nucleic acid ESTs are not supported by a specific asserted utility because the disclosed uses of these compositions are not specific and are generally applicable to any nucleic acid. . . Neither the specification as filed nor any art of record discloses or suggests any property or activity for the nucleic acid and/or protein

> compounds(s) such that another non-asserted utility would be well established for the compounds.

Office Action mailed August 15, 2001, Paper No. 14, pages 3-4.

It is well-established that "when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown." *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 USPQ 592, 598 (Fed. Cir. 1983). The present specification describes many objectives that are met by the present invention including, but not limited to providing a substantially purified nucleic acid sequence which encodes a maize or soybean enzyme or fragment thereof selected from (1) a triose phosphate isomerase (SEQ ID NO 11); (2) a vacuolar H^+ translocating-pyrophosphatase (SEQ ID NO 446); (3) a sucrose synthase (SEQ ID NO 935); (4) a hexokinase (SEQ ID NO 1108); (5) a fructose 1,6-bisphosphate aldolase (SEQ ID NO 2042); (6) a fructose 6-phosphate 2-kinase (SEQ ID NO 2166); (7) an invertase (SEQ ID NO 2252); (8) a fructokinase (SEQ ID NO 2644); (9) a NDP-kinase (SEQ ID NO 2681); and (10) a UDP-glucose pyrophophorylase (SEQ ID NO 2753), or fragments thereof. *See Specification*, Summary of the Invention, page 24.

The Office Action asserts that Applicants have not disclosed or suggested any property or activity for the nucleic acids. Applicants respectfully disagree. The specification provides evidence based on sequence identity (Table A) that the disclosed genes encode polypeptides having specified enzymatic activity. Moreover, the specification indicates by way of EC Classification designations that the specified enzymes are of enzymatic classifications well-known in the art. As such, it is submitted that the functionality of the claimed nucleic acid molecules is disclosed, and that sequence homology is indeed an adequate and predictable indicator of such functionality. Thus, based on such teachings, one of ordinary skill in the art would immediately appreciate the usefulness of the claimed nucleic acid molecules.

An examiner must accept a utility asserted by an applicant unless the Office has evidence or sound scientific reasoning to rebut the assertion. *See In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). "More specifically, when a patent application claiming a nucleic acid asserts a specific, substantial, and credible utility, and bases the assertion upon homology to existing nucleic acids or proteins having an accepted utility, the asserted utility must be accepted by the examiner unless the Office has sufficient evidence or sound scientific

reasoning to rebut such an assertion." Federal Register 66(4):1096, Utility Guidelines (2001). "[A] 'rigorous correlation' need not be shown in order to establish practical utility; 'reasonable correlation' is sufficient." *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1565, 39 USPQ2d 1895, 1900 (Fed. Cir. 1996).

As such, an examiner "must do more than question operability – [the examiner] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 USPQ 664, 666 (CCPA 1975); *see In re Brana*, 51 F.3d 1560, 1567, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995); MPEP § 706.03(a)(1). No such factual reasons have been provided. The utilities disclosed by Applicants must be accepted as factually sound unless and until the Patent Office provides factual reasons that undermine the credibility of the assertion. Therefore, the Office has not met the requisite burden to impose a 35 USC § 101 rejection.

In sum, Applicants have asserted substantial, specific utilities for the claimed nucleic acid molecules of the invention, and absent specific evidence to the contrary, this assertion must be accepted. Applicants have asserted a number of utilities for which the nucleic acids molecules of the invention can be used. These include, but are not limited to, determining the expression levels of the specified enzymes involved in the sucrose pathway in plants (pages 42-46); detecting mutations in the genes encoding these enzymes (page 46-49); and producing plants with altered expression of these enzymes (page 49-54). As such, Applicants have met their burden in establishing specific, "real-world" utilities for the claimed invention.

In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by specific and well-established utilities as disclosed in the specification. As such, withdrawal of this rejection is respectfully requested.

III. Rejection under 35 USC § 112, 1st Paragraph, Enablement

Claims 1-2 stand rejected under 35 USC § 112, 1st Paragraph because the claimed invention is allegedly not supported by either a specific and substantial asserted utility or a well established utility, and thus one of ordinary skill in the art would not know how to use the invention. This rejection is traversed for the reasons discussed above with regard to the 35 USC §101 rejection. As such, it is submitted that the specification enables one of skill in the art to use

the invention in accordance with the asserted specific and substantial utilities discussed above. Accordingly, withdrawal of this rejection is respectfully requested.

Moreover, it is submitted that the Examiner has not met the evidentiary burden to impose an enablement rejection for failure to enable one of skill to use the invention. A specification that discloses how to use a claimed invention "must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein." *In re Brana*, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) (*quoting In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA. 1971) (emphasis in original)). It is also well-established that "the enablement requirement is met if the description enables any mode of making and using the invention." *Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 USPQ2d 1705, 1719 (Fed. Cir. 1998) (emphasis added) (*quoting Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 USPQ2d 1300, 1304 (Fed. Cir. 1991)).

The present specification indeed discloses how to use the claimed invention as discussed above. The Office Action has failed to provide specific evidence supporting this rejection, nor any specific explanation of why the specification allegedly fails to enable these uses. *See In re Wright*, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 USPQ 306, 307 (Bd. App. 1981) ("pure conjecture" does not substantiate rejection for lack of enablement).

Accordingly, for at least these reasons, the enablement rejection under 35 USC § 112, 1st paragraph, is traversed, and withdrawal of this rejection is respectfully requested.

IV. Rejection under 35 USC § 112, 1st Paragraph, Written Description

Claims 1-2 stand rejected under 35 USC §112, 1st paragraph, as allegedly containing subject matter which was not described in the specification in a manner that reasonably conveys to one of ordinary skill in the art that the inventors had possession of the claimed invention at the time of filing. This rejection is respectfully traversed for at least the reasons which follow.

The Office Action acknowledges that SEQ ID NOs: 11, 446, 1108, 2042, 2166, 2252, 2644, 2681, and 2753 meet the written description requirement. However, in support of this rejection, the Office Action alleges:

> claims 1 and 2 are directed to encompass gene sequences of SEQ ID NOs: 11, 446, 935, 1108, 2042, 2166, 2252, 2644, 2681, and 2753[,] corresponding sequences from other species, mutated fragment sequences, allelic variants, splice variants, and so forth given the generic nature of claim 1.

Office Action at page 6.

Initially, the purpose of the written description requirement is simply to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *See Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 USPQ2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 USPQ2d 1578, 1581 (Fed. Cir. 1996). In accordance with this purpose, Applicants need not "describe," in the sense of Section 112, all things that are encompassed by the claims. To contend otherwise would contradict established jurisprudence, which teaches that a patent may be infringed by technology developed after a patent issues. *United States Steel Corp. v. Phillips Petroleum Co.*, v865 F.2d 1247, 1251, 9 USPQ2d 1461, 1464 (Fed. Cir. 1989).

A related and equally well-established principle of patent law is that claims "may be broader than the specific embodiment disclosed in a specification." *Ralston Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (*quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 USPQ 323, 326 (CCPA. 1981)). Thus, simply because the claimed nucleic acid sequences may also include sequences from other species does not require that Applicants describe each and every one of these molecules. Further, "a description as filed is presumed to be adequate, unless and until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption." *Federal Register* 66(4):1107, Written Description Guidelines (2001). In this regard, the Examiner is required to disclose "express findings of fact which support the lack of written description conclusion." *Id.*

The present claims are directed to the genus of nucleic acid molecules which encode specified *maize or soybean* enzymes, or fragments thereof. Applicants have provided detailed chemical structures of the claimed nucleic acid sequences, as well as additional information about the encoded enzymes. These sequences provide "structural feature[s] possessed by members of the [claimed] genus that distinguish[] them from others." *Regents of the University*

of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). In contrast to the mere name "cDNA" provided in *Eli Lilly*, Applicants have provided detailed chemical structures. For at least this reason, it is respectfully submitted that the present claims meet the written description provision under 35 USC § 112, 1st paragraph.

The use of open claiming language (comprising) or semi-open claiming (consisting essentially of) does not alter the fact that a skilled artisan would readily envision adequate written description support. The fact that nucleic acid sequences may be added to either end of the recited sequence is beside the point. Applicants have therefore reasonably conveyed to one skilled in the art possession of the claimed invention, even when additional sequences are added to either end. Indeed, as disclosed in the specification on pages 61, the additional of, for example, detectable labels or extra nucleotides are readily envisioned by those of ordinary skill upon reading the present specification.

Additionally, "it may not be necessary to enumerate a plurality of species if a genus is sufficiently identified in an application by 'other appropriate language.'" *Elli Lilly* at 1569. In the present case, it is submitted that the disclosure of a limited number of nucleic acid sequences encoding specified enzymes or fragments thereof in combination with "other appropriate language" in fact does provide sufficient written description for claims within the genus. Such "other appropriate language" is found, *e.g.*, in the form of sequence identity and numerous methodologies to obtain additional sequences. Therefore, it is clear that one of ordinary skill in the art would recognize that Applicants were in possession of the genus of the specified *maize and soybean* enzyme encoding genes.

Accordingly, for at least the foregoing reasons, the rejection under 35 USC. §112, 1st paragraph, written description, is traversed, and withdrawal of this rejection is respectfully requested.

V. Rejections under 35 USC § 112, 2nd Paragraph

Claims 1-2 stand rejected under 35 USC § 112, 2nd Paragraph for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Withdrawal of these rejections is respectfully requested for the reasons which follow.

Claim 1 stands rejected due to the recitation of the phrase "or fragment thereof". The Office Action alleges that such phrase is vague and indefinite. More particularly, the Office Action sets forth two possible interpretations, one referring to an encoding fragment and another to a fragment without a coding requirement. While not agreeing with either of these interpretations, Applicants submit that the phrase "or fragment thereof" refers to the encoded enzyme rather than the nucleic acid molecule. The claims have been amended to clarify such reference. It is noted that such amendment is for clarification purposes only, and is not intended to narrow the scope of the claim in any respect. As such, it is submitted that claim 1 complies with 35 USC §112, 2nd Paragraph, and withdrawal of this rejection is respectfully requested.

Claim 2 stands rejected because it is allegedly vague and indefinite as to what sequence belongs to what enzyme named in claim 1. Applicants submit that based on the teachings of the specification (see, *e.g.*, Table A), one of ordinary skill in the art would be apprised of the functionality attributed to each of the claimed sequences. However, in order to expedite prosecution, claim 2 has been amended to include an indication of the specified enzymes. It is noted that such amendment is for clarification purposes only, and is not intended to narrow the scope of the claim in any respect. As such, it is submitted that claim 2 complies with 35 USC §112, 2nd Paragraph, and withdrawal of this rejection is respectfully requested.

VI. Rejection under 35 USC § 102(b)

Claim 1 stands rejected under 35 USC § 102(b) as allegedly being clearly anticipated by product oligomers of the Sigma Chemical 1990 Catalog. This rejection is respectfully traversed for the reasons which follow.

As described above with reference to the 35 USC § 112, 2nd Paragraph rejections, the phrase "or fragment thereof" refers to a fragment of the claimed enzymes. Accordingly, the claimed nucleic acid molecules encode a specified enzyme or fragment of the enzyme. In this regard, the Sigma Chemical 1990 Catalog does not disclose a nucleic acid molecule encoding at least a fragment of the claimed enzymes. Therefore, it is submitted that claim 1 is not anticipated by the product oligomers taught by the Sigma Chemical 1990 Catalog, and withdrawal of this rejection is respectfully requested.

VII. Objection to the Disclosure

This disclosure is objected to because it contains embedded hyperlinks and/or other forms of browser-executable code. The specification has been amended to remove such embedded hyperlinks. As such, withdrawal of this objection is respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is now in condition for allowance, and notice of such is respectfully requested.

The Examiner is encouraged to contact the undersigned should any additional information be necessary for allowance.

Respectfully submitted,

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Marked up version of the specification and claims

In the specification:

On page 19 of the specification, please delete the second full paragraph and replace it with the following amended paragraph:

-- Similarity analysis includes database search and alignment. Examples of public databases include the DNA Database of Japan (DDBJ) [(http://www.ddbj.nig.ac.jp/);] (www.ddbj.nig.ac.jp); Genebank [(http://www.ncbi.nlm.nih.gov/Web/Search/Index.htlm);] (www.ncbi.nlm.nih.gov/Web/Search/Index.html); and the European Molecular Biology Laboratory Nucleic Acid Sequence Database (EMBL) [(http://www.ebi.ac.uk/ebi_docs/embl_db/embl-db.html)] (www.ebi.ac.uk/ebi_docs/embl_db/embl-db.html). Other appropriate databases include dbEST [(http://www.ncbi.nlm.nih.gov/dbEST/index.html)] (www.ncbi.nlm.nih.gov/dbEST/index.html), SwisProt [(http://www.ebi.ac.uk/ebi_docs/swisprot_db/swisshome.html)] (www.ebi.ac.uk/ebi_docs/swisprot_db/swisshome.html), PIR [(http://www-nbrt.georgetown.edu/pir/)] (www.nbrt.georgetown.edu/pir), and The Institute for Genome Research [(http://www.tigr.org/tdb/tdb.html)] (www.tigr.org/tdb/tdb.html). --

In the claims:

Please cancel claims 3-6 without prejudice or disclaimer.

Please amend claims 1 and 2 as follows:

1. (Amended) A substantially purified nucleic acid molecule that encodes a maize or a soybean enzyme or fragment [thereof] of said maize or soybean enzyme, wherein said maize or soybean enzyme is selected from the group consisting of:

(a) triose phosphate isomerase;

(b) fructose 1,6-bisphosphate aldolase;

[(c) fructose 1,6-bisphosphate;]

[(d)] (c) fructose 6-phosphate 2-kinase;

[(e) phosphoglucoisomerase;]

[(f)] (d) vacuolar H^+ translocating-pyrophosphatase;

[(g) pyrophosphate-dependent fructose-6-phosphate phosphotransferase;]

[(h)] (e) invertase;

[(i)] (f) sucrose synthase;

[(j)] (g) hexokinase;

[(k)] (h) fructokinase;

[(l)] (i) NDP-kinase;

[(m) glucose-6-phosphate 1-dehydrogenase

(n) phosphoglucomutase;] and

[(o)] (j) UDP-glucose pyrophophorylase.

2. (Amended) The substantially purified nucleic acid molecule according to claim 1, wherein said nucleic acid molecule comprises a nucleic acid sequence selected from the group consisting of [SEQ ID NO; 1 through SEQ ID NO: 2814] SEQ ID NOs: 11, 446, 935, 1108, 2042, 2166, 2252, 2644, 2681, and 2753, wherein said nucleic acid sequence encodes at least a fragment of a maize or soybean triose phosphate isomerase; vacuolar H^+ translocating-pyrophosphatase; sucrose synthase; hexokinase; fructose 1,6-bisphosphate aldolase; fructose 6-phosphate 2-kinase; invertase; fructokinase; NDP-kinase; and UDP-glucose pyrophophorylase, respectfully.

Please add new claims 7-17.